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APPLICATION NO.	FI	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
09/890,778	C	01/24/2002	Thorsten Siess	IMPEL .57972	APEL .57972 7976	
27629	7590	08/16/2004		EXAM	EXAMINER	
		N LEE & UTE	BAXTER,	BAXTER, JESSICA R		
	GATE, SUITE 1550 CH, CA 90802			ART UNIT	PAPER NUMBER	
	,			3731	<del>-</del> -	

DATE MAILED: 08/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)	Cd			
	09/890,7.78	SIESS ET AL.	( <b>/</b> \			
Office Action Summary	Examiner	Art Unit				
	Jessica R Baxter	3731				
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with th	e correspondence add	ress			
A SHORTENED STATUTORY PERIOD FOR REPL' THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.1: after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply by within the statutory minimum of thirty (30) will apply and will expire SIX (6) MONTHS for cause the application to become ABANDC	e timely filed  days will be considered timely, rom the mailing date of this cor DNED (35 U.S.C. § 133).	nmunication.			
Status						
1) Responsive to communication(s) filed on 01 Ju	<u>une 2004</u> .					
2a) ☐ This action is FINAL. 2b) ☒ This	action is non-final.					
3) Since this application is in condition for allowar	nce except for formal matters,	prosecution as to the	merits is			
closed in accordance with the practice under E	Ex parte Quayle, 1935 C.D. 11	, 453 O.G. 213.				
Disposition of Claims						
4) Claim(s) 8-12,18 and 19 is/are pending in the	application.					
4a) Of the above claim(s) is/are withdraw	wn from consideration.					
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>8-12, 18,19</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/o	r election requirement.					
Application Papers						
9) The specification is objected to by the Examine	er.					
10) The drawing(s) filed on is/are: a) acc	epted or b)□ objected to by the	ne Examiner.				
Applicant may not request that any objection to the	drawing(s) be held in abeyance.	See 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)☐ The oath or declaration is objected to by the E	kaminer. Note the attached Off	fice Action or form PT	O-152.			
Priority under 35 U.S.C. § 119						
12) ☐ Acknowledgment is made of a claim for foreign a) ☐ All b) ☐ Some * c) ☐ None of:		9(a)-(d) or (f).				
1. Certified copies of the priority document		notion No				
<ul><li>2. Certified copies of the priority document</li><li>3. Copies of the certified copies of the priority</li></ul>			Stane			
<ol> <li>Copies of the certified copies of the prio application from the International Burea</li> </ol>		cived iii tiiis ivationai v	Stage			
* See the attached detailed Office action for a list	·	eived.				
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summ					
2) D Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Ma	il Date nal Patent Application (PTO	-152)			
<ol> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)</li> <li>Paper No(s)/Mail Date</li> </ol>	6) Other:	arr aton Application (1110	. 32,			

#### **DETAILED ACTION**

#### Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 1, 2004 has been entered.

## Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 3. Claims 8, 9 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/37697 to Rau et al.

Rau discloses a device comprising a micro axial pump fastened to a catheter (13) and having a tubular pump portion (14) comprising a pump ring (15) and a tubular cannula (25) with a distal axial inlet and a proximal radial outlet (16); and a dilating device (20a) surrounding the pump portion.

Regarding the limitation "wherein said dilating device is configured for breaking up a stenosis of a cardiac valve upon deployment while positioned within said cardiac valve", Rau discloses a balloon as a dilating device. There appears to be no structural difference between applicant's claimed device and Rau's disclosed device. The device of Rau is capable of opening up a stenosed valve.

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## Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 10, 11, 12 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/37697 to Rau et al. in view of U.S. Patent No. 4,808,165 to Carr.

Rau discloses the claimed invention except for the particular pressure to which the balloon may be inflated. Carr teaches that a balloon may be inflated to at least 1.0 bar in order to be able to inflate within a stenosed valve. These high pressures are necessary to open the stenosed valve (Column 1 lines 34-40). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Rau with the high inflation pressure of Carr in order to allow the device of Rau to dilate a stenosed valve.

### Response to Arguments

6. Applicant's arguments with respect to claims 8, 9 and 19 have been considered but are moot in view of the new ground(s) of rejection.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott or Shaver can be reached on 703-308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica R Baxter Examiner Art Unit 3731

> DAVID O. REIP PRIMARY EXAMINER

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